**OMB 0910-0337**

SUPPORTING STATEMENT

A. JUSTIFICATION

1. Circumstances Making the Information Collection Necessary.

The Animal Drug Availability Act (ADAA) of October 9, 1996, amended section 512 of the FD&C Act to replace the system for the approval of specific medicated feed with a general licensing system for feed mills.

Before passage of the ADAA, medicated feed manufacturers were required to obtain approved Medicated Feed Applications (MFAs) in order to manufacture certain types of medicated feeds. An individual approved MFA was required for each and every applicable medicated feed. The ADAA streamlined the paperwork process for gaining approval to manufacture medicated feeds by replacing the MFA system with a facility license for each medicated feed manufacturing facility. Implementing regulations are at 21 CFR Part 515.

We are requesting OMB approval for information collection under the following citations:

**21 CFR 515.10(b) Reporting**

Specifies requirements for submitting a completed medicated feed mill license application using Form FDA 3448.

**21 CFR 515.11(b) Reporting**

Specifies requirements for supplemental medicated feed mill license applications for a change in ownership and/or a change in address for the facility using Form FDA 3448

**21 CFR 515.23 Reporting**

Sets forth written requirements for for voluntary revocation of a medicated feed

mill license by the sponsor of that facility on the grounds that the facility is no longer manufacturing medicated animal feed.

**21 CFR 515.30(c) Reporting**

Details requirements for filing a request for a hearing by a sponsor to give reasons why a medicated feed mill license should not be refused or revoked.

**21 CFR 515.305(b) Recordkeeping**

Requires maintenance of approved labeling for each Type B and Type C medicated animal feed being manufactured.

We are also requesting approval of Form FDA 3448.

2. Purpose and Use of the Information

We will use the information required from the medicated feed manufacturing facility, in accordance with 21 CFR 515.10(b), to determine if a medicated feed mill license application will be approved or denied. Form FDA 3448 will be used to certify the information.

3. Use of Information Technology and Burden Reduction.

We have assembled the list of licensees in a computerized data base available on the CVM Home Page on the Internet. The Home Page also contains information on licensing and a license application, Form FDA 3448.

4. Efforts to Identify Duplication and Use of Similar Information

Each medicated feed manufacturing facility is requested to submit data to obtain a license. Data collected is site specific, so there is no duplication of efforts.

5. Impact on Small Business or Other Small Entities

The proposed collection of information carries the same burden for small or large firms. The data collection is minimal.

6. Consequences of Collecting the Information Less Frequently.

Medicated feed manufacturing facilities will not be allowed to enter the market if the information is not submitted. This is a one time submission.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

All of the reporting requirements are consistent with 5 CFR 1320.5

8. Efforts to Obtain Comments on the Information Collection Before Submission to OMB.

In the **Federal Register** of July 26, 2000, (65 FR 45987), FDA published a 60 day notice concerning the proposed extension of this collection of information and requested comments. In response to this notice, no comments were received on the estimated annual reporting and recordkeeping burden. Also,the American Feed Industry Association, which is an industry association of feed mills, and the Animal Health Institute, fully support the new licensing system, as indicated by their support of the legislative initiative and the passage of the Animal Drug Availability Act of 1996 (ADAA).

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9. Explanation of Any Payment or Gift to Respondent

There are no payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondent

Information will be kept confidential in accordance with FDA's public information regulations in 21 CFR Part 20.

11. Justification for Sensitive Questions

The information collection does not involve any questions of a sensitive nature.

12. Estimates of Hour Burden to Respondents

The estimated annual reporting and recordkeeping burden on industry is 72 hours as shown in the tables below. Industry estimates it takes about 1/4 hour to submit the application. We estimate 175 original and supplement applications, and voluntary revocations for a total of 44 hours (175 submissions x 1/4 hour). An additional 3 hours is added for the rare notice of opportunity for a hearing to not approve or revoke an application. Finally,we estimate 25 hours for maintaining and retrieving labels as required by 21 CFR 510.305. We estimated 1/4 hour for each of approximately 100 licensees. Thus the total burden for reporting and recordkeeping is 72 hours.

Table 1 - Estimated Annual Reporting Burden

| 21 CFR | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|---|---|---|---|---|---|
| 515.10 | 100 | 1 | 100 | 0.25 | 25 |
| 515.11 | 25 | 1 | 25 | 0.25 | 6.25 |
| 515.23 | 50 | 1 | 50 | 0.25 | 12.25 |
| 515.30 | 0.15 | 1 | 0.15 | 24 | 3.6 |
| Total Burden Hours | | | | | 47.1 |

Table 2 - Estimated Annual Recordkeeping Burden

| 21 CFR | No. of Recordkeepers | Annual Frequency per Recordkeeping | Total Annual Records | Hours per Recordkeeper | Total Hours |
|---|---|---|---|---|---|
| 510.305(b) | 100 | 1 | 100 | 0.25 | 25 |

13. Estimate of Other Total Cost Burden to Respondents and Recordkeepers

Total annual cost burden is included in the preceding paragraph. There are no additional costs to respondents.

14. Annualized Cost to the Federal Government

We estimate that it will take us 40 minutes to process each of the approximately 175 original applications, supplemental applications and voluntary revocations in a years. This would result in

approximately 117 hours (2/3 hour x 175 applications).

15. Explanation of Program Changes or Adjustments

The reduction (adjustment) in the reporting burden, from 500 hours down to 72 hours, is due to a lesser number of respondents. Licensing is a one time requirement. The initial burden of 500 hours represented the first year when established firms were submitting license applications. We estimated approximately 175 new applications for each succeeding year, thus a current burden of 72 hours.

16. Plans for Tabulation and Publication and Project Time Schedule.
Information is not to be published for statistical use.